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(54) **POLYSILICONE BASE FOR SCAR TREATMENT**

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(57) **ABSTRACT**

A polysilicone base for medical and cosmetic compositions includes a dimethicone fluid, a volatile cyclosiloxane, a silicone elastomer, and nanoparticulate silica. The polysilicone base may also include one or more therapeutic agents for reducing the formation and appearance of scar tissue at the site of a wound. The polysilicone base is spreadable, but does not run off of the wound site. The polysilicone base is phase-stable, in that it does not separate into phases.

2 Claims, No Drawings

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POLYSILICONE BASE FOR SCAR TREATMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Patent Application No. 61/914,168, filed on Dec. 10, 2013, and U.S. Provisional Patent Application No. 62/028,915, filed on Jul. 25, 2014, the disclosures of the aforesaid provisional patent applications being incorporated by reference herein.

FIELD OF INVENTION

The present invention relates to the fields of cosmetic or medical preparations, more specifically to preparations including a polysilicone base for the treatment and inhibition of scar tissue and stretch marks, or as a wound dressing.

BACKGROUND OF INVENTION

Polysilicone compositions have a variety of uses in the skin care industry, for example, as an emollient (also referred to as a "moisturizer"), as a skin protectant, as a cosmetic base, and as a vehicle for bioactive compounds. Polysilicone compositions are also useful in reducing the extent and appearance of scar tissue remaining after surgery or injury to the skin, or from skin conditions such as acne. They can also be used to reduce the appearance of uneven skin textures such as fine lines or acne.

An undesirable property of polysilicone compositions is that they can separate into phases, especially when cosmetic or bioactive compounds are added. This phase separation seriously reduces the usefulness of the composition, particularly as a cosmetic base or vehicle for other compounds.

SUMMARY OF INVENTION

In an embodiment of the present invention, a polysilicone base for application to the skin comprises a blend of polysilicones having different chemical structures and physical properties. In some embodiments, additional substances may be included in the polysilicone base to provide the polysilicone base with desirable rheological properties. In some embodiments, additional substances (e.g., emollients, skin conditioning agents, emulsifying agents, humectants, anti-oxidants, sunscreens, and antibiotic agents or other drugs) may be included in the polysilicone base to provide the polysilicone base with desirable medical, cosmetic, or aesthetic properties. In some embodiments, the polysilicone base is phase stable (i.e., it does not separate into phases).

In some embodiments, the polysilicone base, without further additives, may be applied to injured skin to minimize the appearance of scar tissue. In some embodiments, the polysilicone base may be applied to scar tissue to soften and reduce the scar tissue. In some embodiments, additional substances may be included in the polysilicone base to promote wound healing.

Embodiments of the present invention also include methods of making the polysilicone base of the present invention, and methods of using the polysilicone base of the present invention.

BRIEF DESCRIPTION OF FIGURES

Figures are not provided with the present disclosure, which is directed to a composition of matter and methods of making and using same.

DETAILED DESCRIPTION OF THE INVENTION

An embodiment of the present invention comprises a blend polysilicones, including medical grade polysilicones, selected to be applied to the skin in a spreadable form (e.g., as an ointment). The polysilicones may also be selected to provide the polysilicone base with desirable aesthetic properties (e.g., "look and feel"). It is desirable that the polysilicone base spread easily (spreadability), yet remain at the location at which it is applied, rather than running off of the application site. It is also desirable that the polysilicone base not irritate the skin, but provide the skin with a pleasant feel after it is applied (e.g., a smooth, silky, and non-greasy after-feel). The polysilicone base should also be stable, in that the components will not separate into phases. Other polysilicones which are not necessarily medical-grade, or other non-medical grade substances, may be included in the polysilicone base with the medical-grade polysilicones to provide the polysilicone base with the aforesaid properties.

In some embodiments, the polysilicones for the polysilicone base are selected to minimize the formation of scar tissue on skin damaged by such causes as cuts, burns, acne, or surgical wounds, and/or to soften and reduce scar tissue that has already formed. In some embodiments, substances with wound-healing properties may be added to the polysilicone base.

A polysilicone base according to an embodiment of the present invention includes: a blend of dimethicones of various viscosities and molecular weights; a volatile cyclosiloxane; a silicone elastomer; and a nanoparticulate mineral. Table 1 presents the composition of a polysilicone base according to an embodiment of the present invention, with the amounts of the various components shown as ranges.

TABLE 1

Compound	% by Weight
Stearoxymethicone/dimethicone copolymer	23.00-35.00
Cyclopentasiloxane	32.00-49.00
Dimethicone (100 cSt)	17.00-26.00
Dimethicone (1,000 cSt)	2.00-5.00
Dimethicone (60,000 cSt)	1.00-5.00
Fumed silica	0.40-0.80

Dimethicones are used in the polysilicone base as an active skin protectant and moisturizer. The physical properties of the dimethicones vary with viscosity and molecular weight, and may be used to impart a range of characteristics to the polysilicone base. At lower viscosities (e.g., 100 cSt), the dimethicones impart spreadability to the polysilicone base and dissolve high viscosity polysilicones that may otherwise not flow or be spreadable. At higher viscosities (e.g., 1,000 cSt), the dimethicones improve the feel of the polysilicone base, and provide a water-repellant protective barrier, while allowing the skin to perspire. At yet higher viscosities (e.g., 60,000 cSt), the dimethicones tend to provide a tacky feel to the polysilicone base, and are diluted to maintain the spreadability of the polysilicone base. Embodiments of the present invention may include other polysilicones in place of the

dimethicones discussed above to produce a polysilicone base that has the properties of the exemplary polysilicone bases discussed elsewhere herein.

Cyclopentasiloxane is a volatile cyclic polysilicone that improves the spreadability of the polysilicone base, and provides the skin with a smooth, silky feel after the polysilicone base is applied thereto. In embodiments of the present invention, other volatile polysilicones may be used along with or in place of cyclopentasiloxane to improve the spreadability of the polysilicone base.

Stearoxymethicone/dimethicone co-polymer is a polysilicone elastomer, which tends to prevent phase separation of the various components of the polysilicone base. It also provides sebum absorption and oil control, and a soft-cushioning, powdery after-feel to the polysilicone base. In embodiments of the present invention, other polysilicone materials may be used along with or in place of stearoxymethicone/dimethicone co-polymer to prevent phase separation of the various components of the polysilicone base.

Fumed silica is included in the polysilicone base of Table 1 to further improve the rheology and thixotropy of the polysilicone base. Fumed silica tends to be composed of silica particles with high specific surface areas and sizes in the nanometer range. In embodiments of the present invention, other rheologic or thixotropic agents may be used along with or in place of fumed silica to form a polysilicone base having similar rheological or thixotropic properties to the exemplary polysilicone bases discussed herein.

The polysilicone base of the present invention may comprise other dimethicones, volatile cyclosiloxanes, polysilicone elastomers, and nanoparticulate minerals than those listed above. Surfactants, such as lauryl alcohol ethoxylates may be added to the polysilicone base in small amounts as emulsifiers to aid the elastomers in preventing separation of the components. In some embodiments, additional substances may be included in the polysilicone base to promote wound healing, or to add color or scent to the polysilicone base. When such additional substances are included in the polysilicone base, the amounts of the polysilicone compounds may be adjusted, or small amounts of other polysilicones added, to maintain the stability and rheological properties of the polysilicone base.

An exemplary embodiment of the polysilicone base of the present invention has the composition shown in Table 2.

TABLE 2

Compound	Exemplary Trade Name	% by Weight
Stearoxymethicone/ dimethicone copolymer (98-99%)/ Laureth-12 (1-2%)	Gransil EP-BD (Grant Industries)	29.00
Cyclopentasiloxane	ST Cyclomethicone 5-NF (Dow Corning)	40.80
Dimethicone (100 cSt)	Q7-9120 Silicone Fluid 100 CS #771324 (Dow Corning)	22.00
Dimethicone (1,000 cSt)	Q7-9120 Silicone Fluid 1,000 CS #791955 (Dow Corning)	4.50
Dimethicone (60,000 cSt)	KF96H 60,000CS (DM-FLUID 60,000CS) (Shin-Etsu)	3.00
Fumed silica (specific surface area of 175-225 m^2/g)	Aerosil 200 (Evonik)	0.70
TOTAL		100.00

The exemplary polysilicone base has a viscosity in the range of 2,200,000 to 3,200,000 cSt after 24 hours and spreads easily over the skin, yet remains at the location at which it is applied, rather than running off of the application site. The exemplary polysilicone base is expected to be non-irritating in normal use. The exemplary polysilicone base is phase stable.

In the exemplary polysilicone base, and in other embodiments of the present invention, one or more of the component polysilicones are recognized in the medical arts as being medical grade materials. In an embodiment of the present invention, the dimethicones having lower viscosities (e.g., 100 cSt and 1,000 cSt) and the cyclopentasiloxane are selected from among available medical grade materials. In the exemplary polysilicone base, and in other embodiments of the present invention, about 40% of the polysilicones are volatile polysilicones.

In a method of making a polysilicone base having a composition such as that of Table 1, the dimethicones, volatile cyclosiloxane, and silicone elastomer may be blended together in a sanitized vessel under anhydrous conditions, then homogenized. After further blending, the nanoparticulate mineral may be added, with concurrent mixing, and the resulting mixture homogenized. Additional blending may be needed to bring the mixture to the desired initial viscosity. Suitable blending rates and equipment, as well as blending times and temperatures, may be readily ascertained by those having ordinary skill in the art and possession of the present disclosure.

In a method of making the polysilicone base of Table 2, the desired amounts of the listed dimethicones, volatile cyclosiloxane, and silicone elastomer are added to a cleaned and sanitized vessel, blended, then homogenized. The fumed silica may then be added, with mixing, and the mixture may then be homogenized. A sample of the homogenized mixture may be tested for its initial viscosity. It the initial viscosity is out of specification (e.g., 1,700,000 to 2,500,000 cSt), additional blending or homogenization may be performed. The blending steps described above are carried out under anhydrous conditions in a nominal temperature range that will minimize the release of the volatile components. Suitable blending rates and equipment, as well as blending times and temperatures, may be readily ascertained by those having ordinary skill in the art and possession of the present disclosure. Additional components (e.g., substances to modify the aesthetic properties of the polysilicone base, or bioactive substances) may be mixed into the base.

Embodiments of the present invention may be used to inhibit the formation or reduce the appearance of scar tissue, which normally forms during the natural healing of wounds or other injuries. The scar tissue is formed from collagenous connective tissue that grows into the site of the wound. Hypertrophic scars form as raised areas or lumps above the wounded area of the skin. Such scars are formed by the formation of too much collagen relative to normal skin during the healing process. Keloid scars grow beyond the site of the wound, resulting in reddish tumor-like growths. Such a scar consists primarily of collagen. The growths are benign (i.e., not cancerous), but often have an unpleasant appearance or cause an itchy or burning sensation. Keloid scars may form during wound healing, but may also form spontaneously, with no known cause. Embodiments of the scar treatment base of the present invention, with or without therapeutic additives, may be applied over wounds to inhibit scar formation, or applied to scars that have already formed to reduce their appearance.

In a first method of using the polysilicone base of the present invention, the user applies a thick layer of the polysilicone base to the injured skin. The polysilicone base

remains in place during the healing process, or until it is removed. In a second method of the using the polysilicone base of the present invention, the polysilicone base is applied to scar tissue and gently massaged to aid in softening and flattening the scar tissue.

It will be understood by those having ordinary skill in the art and possession of the present disclosure that the embodiments described herein are merely exemplary in nature and that a person skilled in the art may make many variations and modifications thereto without departing from the scope of the present invention. All such variations and modifications, are intended to be included within the scope of the invention as described in the attached claim(s).

We claim:

1. A polysilicone base for medical and cosmetic compositions, comprising:

a first dimethicone fluid having a viscosity of about 100 cSt, said first dimethicone fluid being present in the base in an amount in the range of from about 23% to about 35% by weight;

a second dimethicone fluid having a viscosity of about 1,000 cSt, said second dimethicone fluid being present in said base in an amount in the range of from about 2% to about 5% by weight;

a third dimethicone fluid having a viscosity of about 60,000 cSt, said third dimethicone fluid being present in said base in an amount in the range of from about 1% to about 5% by weight;

a volatile cyclopentasiloxane fluid present in said base in an amount in the range of from about 32% to about 49% by weight;

a stearoxymethicone/dimethicone copolymer present in said base in an amount in the range of from about 23% to about 35% by weight; and

a nanoparticulate silica present in said base in an amount in the range of from about 0.4% to about 0.8% by weight, wherein at least said first and second dimethicones and said volatile cyclopentasiloxane are of types recognized in the medical arts as medical grade materials.

2. The polysilicone base of claim **1**, further comprising at least one therapeutic agent for reducing the formation and/or appearance of scar tissue at a site of a wound.

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